Paper No. 18

UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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Ex parte DIJIA HUANG, BRENDA L. TUDOR
and KIN-FAI YIP

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Appeal No. 1999-2430
Application No. 08/854,440

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ON BRIEF

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Before KIMLIN, WARREN and OWENS, Administrative Patent Judges.

KIMLIN, Administrative Patent Judge.

## DECISION ON APPEAL

This is an appeal from the final rejection of claims 1, 3, 4, 7, 8, 12-16, 18 and 19. Claim 1 is illustrative:

1. A method for correcting ambient temperature effect in biosensors comprising the steps of:

measuring an ambient temperature value;

applying a sample to the biosensors and measuring a current generated in the test sample;
calculating an analyte concentration value utilizing said measured ambient temperature value to thereby increase the accuracy of the analyte determination; and

said step of calculating said analyte concentration value includes the step of converting said measured current to an observed analyte concentration value and calculating a corrected analyte concentration value utilizing the equation:

$$G_2 = \frac{G_1 - (T_2^2 - 24^2) * I2 - (T_2 - 24) * I1}{(T_2^2 - 24^2) * S2 + (T_2 - 24) * S1 + 1}$$

where $G_1$ is said observed analyte concentration value, $T_2$ is said measured ambient temperature value and I1, I2, S1, and S2 are set values and are experimentally determined coefficients.

The examiner relies upon the following reference as evidence of obviousness:

Bessman et al. (Bessman) 4,431,004 Feb. 14, 1984

Appellants' claimed invention is directed to a method and apparatus for correcting the ambient temperature effect in biosensors which are used to calculate an analyte, such as glucose, in a sample. The analyte concentration value is calculated by utilizing the recited polynomial equation. According to appellants, use of the claimed equation increases the accuracy of the analyte determination.

Appealed claims 1, 3, 4, 7, 8, 12-16, 18 and 19 stand rejected under 35 U.S.C. § 103 as being unpatentable over Bessman.

We have thoroughly reviewed the respective positions advanced by appellants and the examiner. In so doing, we find

ourselves in agreement with the position espoused by appellants in their Brief. Accordingly, we will not sustain the examiner's rejection.

While there is no dispute that Bessman discloses a method for correcting the ambient temperature effect in biosensors, the examiner appreciates that Bessman does not teach use of the claimed equation. In particular, the examiner recognizes that "[t]he method and apparatus of Bessman et al[.] differs [sic, differ] from the presently claimed invention in that it fails to specify a polynomial, and particularly the presently claimed polynomial, for correcting the measurement responsive to temperature measured by the thermistor" (page 4 of Answer). The examiner points out, however, that Bessman discloses that mathematical techniques are available empirically or theoretically to generate correction functions, and that "[t]he actual function used to correct for oxygen concentration employed may be selected for simplicity, accuracy or convenience" (column 4, lines 27-29). Based on this referenced disclosure, the examiner concludes the following:

> It would have been obvious to one of ordinary skill in the art to generate alternative empirical correlations for temperature correction, as per the teaching of Bessman et al., in order to provide the desired complexity according to afford the corresponding level of accuracy. The empirical fit of correlation data to either logarithmic or polynomial equations was routine and would have been obvious to one of ordinary skill for the above[-]noted temperature correction.

The examiner goes on to explain at page 5 of the Answer that "the only difference between the method and apparatus of Bessman et al[.] as compared with the instant claims is the particular mathematical expression which is utilized to describe the correction data."

At the outset, we note that the examiner states that "the instant claims as a whole are not directed to non-statutory subject matter" (page 4 of Answer, last sentence). Accordingly, although the examiner seems to raise the specter of a patentability issue under 35 U.S.C. § 101, the examiner has refrained from imposing such a rejection. In any event, we refer the examiner to State Street Bank and Trust Co. v. Signature Financial Group Inc., 149 F.3d 1368, 1373-74, 47 USPQ2d 1596, 1600-01 (Fed. Cir. 1998), for the Court's

reasoning regarding the patentability of a mathematical algorithm when it constitutes a practical application and produces a useful, concrete and tangible result.

Regarding the examiner's § 103 rejection, we are not persuaded that the examiner has established the requisite factual foundation for supporting the obviousness of the claimed invention within the meaning of § 103. In re Warner, 379 F.2d 1011, 1017, 154 USPQ 173, 177-78 (CCPA 1967). While the examiner reasons that it would have been obvious for one of ordinary skill in the art to generate alternative empirical correlations for the one disclosed by Bessman, the examiner has not established on this record that polynomial equations, in general, are routine in the art of designing temperature corrections in measuring instruments, let alone in the particular art involving the inventions of Bessman and appellants. In the absence of such a factual finding by the examiner, we must agree with appellants that the examiner has only posited why it would have been obvious for one of ordinary skill in the art to try to find a polynomial expression for use in the system of Bessman. Manifestly, such

an approach is not the proper standard for demonstrating obviousness.

In conclusion, based on the foregoing, the examiner's decision rejecting the appealed claims is reversed.

REVERSED

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| EDWARD C. KIMLIN<br>Administrative Patent Judge | ) | |
| CHARLES F. WARREN<br>Administrative Patent Judge | ) | BOARD OF PATENT APPEALS AND INTERFERENCES |
| TERRY J. OWENS<br>Administrative Patent Judge | ) | |

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Jerome L. Jeffers
P.O. Box 40
Elkhart, IN  46515-6640